

IAP6 Rec'd PCT/PTO 11 AUG 2006

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: La Monica, et al.

10/589180

Serial No. To Be Assigned

Art Unit: \_\_\_\_\_

Filed: August 11, 2006

Examiner: \_\_\_\_\_

For: CARCINOEMBRYONIC ANTIGEN FUSIONS AND  
USES THEREOFCommissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450INFORMATION DISCLOSURE STATEMENT  
UNDER 37 CFR 1.97

Sir:

1. In compliance with 37 C.F.R. 1.97, submitted on the attached form herewith is a list of patents, publications or other information which are requested to be made of record in this application. This Information Disclosure Statement is not an admission that any patent, publication or other information referred to herein is "prior art" for this invention. In accordance with 37 C.F.R. 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. 1.56(b).

2. In accordance with 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

3. Applicants respectfully request that the Examiner initial the attached form after reviewing the pertinence of each reference.

4. Pursuant to 37 C.F.R. 1.98 (a)(2)(ii), copies of each cited U.S. patent and each U.S. patent application publication are not enclosed herewith.

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MERCK &amp; CO., INC.

By \_\_\_\_\_ Date \_\_\_\_\_

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## INFORMATION DISCLOSURE STATEMENT

5. Pursuant to 37 C.F.R. 1.98(d), copies of references listed on the attached form that were submitted to or cited by the Office in a related application upon which the instant application relies for an earlier filing date under 35 U.S.C. 120 are not enclosed. Related application(s) in which references were submitted to or cited by the Office are as follows:

RELATED APPLICATION		
U. S. SERIAL NUMBER	FILING DATE	MERCK CASE

If this is inconvenient, additional copies will be submitted upon request.

6. In accordance with 37 C.F.R. 1.97, (check one)

- ☒ the attached information is filed within three months of the filing date of the captioned case.
- ☐ the attached information is filed more than three months after the filing date but prior to the mailing of a first Office Action on the merits.
- ☐ the attached information is filed before the mailing of a first Office action after the filing of a request for continued examination under §1.114.
- ☐ the attached information is being filed more than three months after the filing date and after the mailing of a first Office Action on the merits, but before the mailing date of a Final Action, Notice of Allowance, or an action that otherwise closes prosecution in the application. The enclosed authorization is therefore given to charge Deposit Account No. 13-2755 for the fee required under 37 C.F.R. 1.17(p).
- ☐ each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Statement.
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- ☐ no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated under 37 C.F.R. 1.56(c) more than three months prior to the filing of this Statement.

Respectfully submitted,

By: Alysia A. Finnegan

Attorney \_\_\_\_\_ For Applicant(s)

Reg. No. 48,878

MERCK & CO., INC.

Patent Dept., RY60-30

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(732)594-2583

Date: August 11, 2006

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*(use as many sheets as necessary)*

**COMPLETE IF KNOWN**

~~10/589180~~

Application Number

**Filing Date**

August 11, 2006

**First Named Inventor**

La Monica, et al.

## Group Art Unit

Examiner Name

Sheet

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of

4

Attorney Docket Number

ITR0073YP

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FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Office	Number	Kind Code (if known)		
		EPC	0 346 710 B1		Miles, Inc.	11/11/1993
		PCT	WO 01/014416 A2		Merck & Co., Inc.	03/01/2001
		PCT	WO 01/24832 A2		Pecher	04/12/2001
		PCT	WO 01/30382 A1		Aventis Pasteus Limited	05/03/2001
		PCT	WO 02/022080 A3		Merck & Co., Inc.	03/21/2002
		PCT	WO 02/38769 A2		Muller	05/16/2002
		PCT	WO 03/059379 A2		Pharmexa	07/24/2002
		PCT	WO 2004/072287 A1		Instituto Di Ricerche Di Biologia Molecolare	08/26/2004
		PCT	WO 2004/092216 A1		Trangene S.A.	10/28/2004
		PCT	WO 2004/099247 A2		Instituto Di Ricerche Di Biologia Molecolare	11/18/2004

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**INFORMATION DISCLOSURE**  
**STATEMENT BY APPLICANT**

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**COMPLETE IF KNOWN****Application Number**

10/589180

**Filing Date**

August 18, 2006

**First Named Inventor**

**La Monica, et al.**

## Group Art Unit

**Examiner Name**

Sheet

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2

Attorney Docket Number

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## U.S. PATENT DOCUMENTS

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## FOREIGN PATENT DOCUMENTS

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Substitute for form 1449B/PTO <b>INFORMATION DISCLOSURE</b>  <b>STATEMENT BY APPLICANT</b>  <i>(use as many sheets as necessary)</i>			<b>COMPLETE IF KNOWN</b>		
			Application Number	10/589180	
			Filing Date	August 11, 2006	
			First Named Inventor	La Monica, et al.	
			Group Art Unit		
			Examiner Name		
Sheet	3	of	4	Attorney Docket Number	ITR0073YP

NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
		Beauchemin, et al., "Isolation and Characterization of Full-Length Functional cDNA Clones for Human Carcinoembryonic Antigen", Mol. and Cell. Biol., Vol. 7, No. 9, pp. 3221-3230, Sept. 1987.
		Benchimol, et al., "Carcinoembryonic Antigen, a Human Tumor Marker, Functions as an Intercellular Adhesion Molecule", Cell, Vol. 57, pp. 327-334, April 21, 1989.
		Berinstein, et al., "Carcinoembryonic Antigen as a Target for Therapeutic Anticancer Vaccines: a Review", J. of Clinical Oncology, Vol. 20, No. 8, pp. 2197-2207, April 15, 2002.
		Chen, et al., "Enhancement of DNA Vaccine Potency by Linkage of Antigen Gene to an HSP70 Gene", Cancer Research, Vol. 60, pp. 1035-1042, February 15, 2000.
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		Chester, et al., "Recombinant anti-carcinoembryonic antigen antibodies for targeting cancer", Cancer Chemother. Pharmacol., Vol. 46 (Suppl) S2-S12, 2000.
		Gold, et al., "Demonstration of Tumor-Specific Antigens in Human Colonic Carcinomata by Immunological Tolerance and Absorption Techniques", J. Exp. Med., Vol. 121, pp. 439-462 (1965).
		Hammarstrom, et al., "Is There a Role for CEA in Innate Immunity in the Colon", Trends in Microbiology, Vol. 9, No. 3, pp. 119-125, 2001.
		Kantor, et al., "Immunogenicity and Safety of a Recombinant Vaccinia Virus Vaccine Expressing the Carcinoembryonic Antigen Gene in a Nonhuman Primate", Cancer Research, Vol. 52, pp. 6917-6925, 1992.
		King, et al., "DNA Vaccines With Single-Chain Fv Fused To Fragment C Of Tetanus Toxin Induce Protective Immunity Against Lymphoma and Myeloma", Nature Medicine, Vol. 4, No. 11, pp. 1281-1286, November 1998.
		Lathe, "Synthetic Oligonucleotide Probes Deduced from Amino Acid Sequence Data", J. Mol. Biol., Vol. 183, pp. 1-12, 1985.
		Liu, et al., "Recombinant Adeno-Associated Virus Expressing Human Papillomavirus Type 16 E7 Peptide DNA Fused with Heat Shock Protein DNA as a Potential Vaccine for Cervical Cancer", J. of Virol., Vol. 74, No. 6, pp. 2888-2894, March 2000.
		Lund, et al., "Signal sequence deletion and fusion to tetanus toxoid epitope augment antitumor immune responses to a human carcinoembryonic antigen (CEA) plasmid DNA vaccine in a murine test system", Cancer Gene Therapy, Vol. 10, pp. 365-376, 2003.
		Montgomery, et al., "Heterologous and Homologous Protection Against Influenza A by DNA Vaccination: Optimization of DNA Vectors", DNA and Cell Biology, Vol. 12, No. 9, pp. 777-783, 1993.
		Padua, et al., "PML-RARA-targeted DNA vaccine induces protective immunity in a mouse model of leukemia", Nature Medicine, Vol. 9, No. 11, pp. 1413-1417, November 2003.

Examiner Signature	Date Considered
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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT***(use as many sheets as necessary)***COMPLETE IF KNOWN**

Application Number	10/589180
Filing Date	August 11, 2006
First Named Inventor	La Monica, et al.
Group Art Unit	
Examiner Name	
Attorney Docket Number	ITR0073YP

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4

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
		Paxton, et al., "Sequence Analysis of Carcinoembryonic Antigen: Identification of Glycosylation Sites and Homology With the Immunoglobulin Supergene Family", Proc. Natl. Acad. Sci. USA, Vol. 84, pp. 920-924, February 1987.
		Renard, et al., "HER-2 DNA and Protein Vaccines Containing Potent Th Cell Epitopes Induce Distinct Protective and Therapeutic Antitumor Responses in HER-2 Transgenic Mice", J. of Immunol., Vol. 171, pp. 1588-1595, 2003.
		Savalyeva, et al., "Plant viral genes in DNA idiotype vaccines activate linked CD4+ T-cell mediated immunity against B-cell malignancies", Nature Biotechnology, Vol. 19, pp. 760-764, August 2001.
		Scholl, et al., "Gene Therapy Applications to Cancer Treatment", J. of Biomed. and Biotech., Vol. 1, pp. 35-47, 2003.
		Screaton, et al., "Carcinoembryonic Antigen, A Human Tumor Marker, Cooperates with Myc and Bcl-2 in Cellular Transformation", J. of Cell Biology, Vol. 137, No. 4, pp. 939-952, May 19, 1997.
		Shiver, et al., "Cytotoxic T Lymphocyte and Helper T Cell Responses following HIV Polynucleotide Vaccination", Annals. New York Academy of Sciences, Vol. 772, pp. 198-208, 1995.
		Su, et al., "Enhanced Induction of Telomerase-specific CD4+ T Cells Using Dendritic Cells Transfected with RNA Encoding a Chimeric Gene Product", Cancer Research, Vol. 62, pp. 5041-5048, September 1, 2002.
		Thompson, et al., "Molecular cloning of a gene belonging to the carcinoembryonic antigen gene family and discussion of a domain model", Proc. Natl. Acad. Sci. USA, Vol. 84, pp. 2965-2969, May 1987.

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